

PROGRAM CONTACT: **SUMMARY STATEMENT**
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Application Number: 1 R21 EB007566-01

Principal Investigator

MURPHY, TIMOTHY P MD

Applicant Organization: QUEQUECHAN ENGINEERING, INC.

Review Group: ZEB1 OSR-B (M1)
National Institute of Biomedical Imaging and Bioengineering Special Emphasis
Panel

Meeting Date: 03/14/2007
Council: MAY 2007
Requested Start: 07/15/2007

RFA/PA: EB06-003
PCC: AITD

Project Title: Percutaneous mesenteric arterial flow modulation as treatment for morbid obesity

SRG Action: **

Human Subjects: 10-No human subjects involved

Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Project Year 1	Direct Costs Requested 223,060
<hr/> TOTAL	<hr/> 223,060

****NOTE TO APPLICANT:** As part of the initial scientific merit review process, reviewers were asked to identify those applications with the highest scientific merit, generally the top half of applications that they customarily review. At the study section meeting, those applications were discussed and assigned a priority score. All other applications, including this application, did not receive a score. Provided is a compilation of reviewers' comments prepared prior to the meeting, without significant modification or editing by NIH staff.

1R21EB007566-01 MURPHY, TIMOTHY

SCIENTIFIC REVIEW ADMINISTRATOR'S NOTE

DESCRIPTION (provided by applicant): Obesity is an epidemic in the U.S. More than half of the U.S. population is overweight, one-third are obese, and more than 5 million adults in the U.S. are categorized as morbidly obese (body mass index >40). Obesity is associated with increased cardiovascular disease risk and mortality. The BROAD, LONG-TERM OBJECTIVES of this project are to improve health in individuals with morbid obesity. The SPECIFIC AIMS are to test a novel approach at inducing weight loss in an animal model by reducing blood mesenteric arterial blood flow thereby not allowing increases in mesenteric blood flow required for digestion after a large meal, the purpose of which is to result in a behavioral change to avoid over-eating. The RATIONALE is that because blood flow in the mesenteric circulation normally increases 3-fold in diastole (the dominant part of the cardiac cycle) after meals, it should be possible to induce a state where blood flow is adequate to maintain bowel viability without symptoms at rest, but not sufficient to accommodate the large increase in flow that is necessary after meals, resulting in abdominal pain and/or diarrhea after large meals. This will result in behavior changes such as avoidance of eating large amounts, thereby producing weight loss. Mesenteric blood flow modulation will be done by a combination of vascular occlusion of the gastroduodenal artery (GDA) and variable flow reduction of the superior (cranial) mesenteric artery (SMA) in pigs using a proprietary stent-graft designed for this purpose, to be placed using percutaneous interventional techniques. The HEALTH-RELATEDNESS is that weight loss lowers the risk of cardiovascular and other health adverse events, and improves quality of life. If effective, the proposed treatment would be appealing for those who are not candidates for invasive gastric bypass surgery, and may prove to be a lower risk alternative to gastric bypass surgery. The RESEARCH DESIGN AND METHODS would be to develop a fabric-covered vascular stent-graft for percutaneous, fluoroscopically-guided placement into the superior (cranial) mesenteric artery of pigs, and occlusion of the GDA with coils. After the prototype is developed and bench-tested, it will be introduced into 10 adult swine, with 10 also undergoing a sham procedure. Post-procedure course will be monitored including dietary intake and weight up to 2 months. We will look for a statistically significant difference in weight change score as a continuous variable as the primary endpoint, and will also examine adverse events, and daily dietary caloric intake pre- and post-procedure. Principal Investigator: Murphy, Timothy, Patrick More than 5 million adults in the U.S., 5% of the adult population, meet the definition of morbid obesity. There may be as many as 2 million people in the U.S. who would be candidates for the proposed treatment, which may be possible with lower cost and substantially lower morbidity and mortality than gastric bypass surgery.

CRITIQUE 1:

Description: The authors propose to build and investigate a new covered stent with constricted central diameter so as to impose gastric ischemia as a means to treat morbid obesity.

SIGNIFICANCE:

Although obesity is an extremely important national problem, it has primarily behavioral and cultural causes. Nevertheless, the use of a more convenient, cheaper, less invasive procedure such as the authors propose has the potential to replace existing invasive surgical procedures and to enable a larger number of people to be treated with a physical intervention for something that is essentially behavioral in nature. Also as the authors admit there are questions of ethics, purposeful induction of pain, and risks of infarction that arise and they argue that the benefit is worth the risk. There is a question as to how many patients would submit to a procedure to induce ischemia where, as the authors state, "the symptoms of this disease include weight loss, malabsorption, anorexia, food fear, and diarrhea." These somewhat contradictory justifications for the project tend to detract from one's enthusiasm for it in terms of its significance.

APPROACH:

The authors approach is to design, manufacture, and test a PTFE-covered, balloon-expandable stent that upon deployment can have a longitudinally-central diameter restriction to reduce blood flow to the superior mesenteric artery (SMA) and simultaneously to use coils to embolize the gastroduodenal artery (GDA). While the authors should be able to achieve their technical goals of creating such a stent and deploying it in a number of test animals, the design procedure appears to be somewhat of a trial-and-error approach. For a new stent of this kind it would seem that to have any justification for long term efficacy and safety one would have to demonstrate through computer simulations using finite element analysis (FEA) that a particular design could achieve its physical goals. Most covered stents and stents in general are placed in abnormal or diseased vessels so one would be concerned about matching the compliance and other mechanical properties of such a new stent with the normal vessel that it is intended to be deployed in. One is also unconvinced that the procedure as the authors claim is totally reversible by simply balloon expanding the new stent so as to enlarge the central diameter. What started out as a normal healthy vessel will never be as such again and one is uncertain as how such a vessel might react years later if it were desired to undo the treatment because the patient might have matured or may no longer have the behavioral problems that originally caused the obesity. Details of the use of the coils to occlude the GDA were also lacking as well as possible long term results from this apparently irreversible procedure.

It is not even certain that the procedure would necessarily have the desired effects in the intermediate term. If there were collateral blood flow then less ischemia would be induced and there might be minimal effect. If there were minimal collateral flow then the risk of infarction would seem to be greater.

There is also a question as to the experience, expertise, and capability of laser cutting the stents in-house since this usually requires great accuracy and dedicated equipment and personnel. It might be less expensive and more advantageous to contract out the laser cutting to facilities that do only such work and who would return electro-polished sample quantities without the learning curve that the in-house facility would appear to have to go through. Additionally, there is no detailed discussion of a possible special balloon that might be needed to expand this new stent so that the diameters are not uniform. Most existing balloon-expandable stents use a non-compliant balloon to expand stents to a somewhat uniform diameter perhaps with a bit of dog-boning; however, for the stent with constriction in middle as proposed by the authors, either a compliant balloon with difficult to predict final expanded diameter, or a non-compliant specially designed balloon to fit the desired final shape would have been used. In either case there are technical problems that the authors do not seem to have considered in detail.

INNOVATION:

The design of the new stent is somewhat innovative; however, much of the technology they propose for the stent presently exists. The application to purposely create blood flow constriction in a normal vessel appears original.

INVESTIGATORS:

Dr. Timothy Murphy is a prominent vascular interventional radiologist who is a principal in the small company Quequechan and he is the director of Vascular Disease Research at Rhode Island Hospital and on the faculty of Brown University. His commitment is 10%. His experience and credentials would appear to be quite appropriate for the clinical and leadership role he plays in the project. L. Bullock, PhD of U. Mass-Dartmouth is a physicist and manager of the Photonics Lab; however, he has no research publications listed since 1973 in his very brief biosketch. It is stated in the proposal that he had some experience in laser cutting stents at one time but the extent of his capability in FEA and leading the design and manufacture of the stents is hard to evaluate from what is stated in the proposal. Other work is to be done by graduate students, laboratory personnel at Rhode Island Hospital animal facilities, and an administrative assistant to Dr. Murphy.

ENVIRONMENT:

Environment appears adequate to the tasks proposed although there is some question regarding the approach, experience, and perhaps the resources needed to adequately laser cut the stents.

OVERALL EVALUATION:

It would seem that even if the proposed stent were able to be satisfactorily made and deployed, the simple animal experiments envisioned to see if a population of 10 farm pigs can be induced to eat less would be hardly conclusive regarding long term efficacy and safety in humans. There are also some questions regarding the techniques proposed for designing and deploying the new stents with the correctly designed balloons as well as some question about the use of in-house facilities for laser cutting the stents. Basically, the authors propose to induce gastric ischemia by constricting healthy vessels with a permanently deployed stent and with embolic coils. It is difficult to be enthusiastic about a proposal to make more accessible a potentially risky alternate physical treatment for what is essentially the behaviorally-caused condition of obesity.

CRITIQUE 2:

SIGNIFICANCE:

The PI proposes to develop a stent graft that can be placed in the superior mesenteric artery endovascularly under image guidance. The stent graft will be balloon inflatable and when inflated will take on a "dog bone" shape with a stenosis in the center such as to restrict blood to the smaller arteries supplying the bowel. The premise is that by constricting the flow through the superior mesenteric it will create a condition similar to the clinical condition of chronic mesenteric ischemia. Patients with that condition have to adapt their eating habits to the condition by eating small amounts of food frequently and therefore lose weight. Obesity in the US has reached epidemic proportion and approximately \$100 billion is spent annually for the treatment of obesity related diseases. Combating obesity is significant.

APPROACH:

The PI proposes two specific aims. In the first aim they will develop a variable diameter stent-graft for introduction in the pig superior mesenteric artery in conjunction with selective embolization of collateral arteries to reduce mesenteric flow. In the second specific aim the device will be placed in a cohort of barnyard swine to compare their weight and caloric intake to a cohort of controls.

The application is essentially proposing to develop a device for a non established animal model and then see if an animal model can be established. What should be done first before embarking on the road of device development is to demonstrate that an animal model exists by using simple coarctations around the mesenteric artery. Also, in the methods section the application does not talk about embolization of collaterals despite the fact that it appears in the first specific aim.

INNOVATION:

BioMEMS Highly innovative application

INVESTIGATORS:

The PI is experienced in endovascular procedures and implantation of stents. The faculty is experienced in the design and fabrication of stents and stent-grafts.

ENVIRONMENT:

The available facilities of the proposing organization and partner are sufficient to execute the proposed project.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS:

N/A

GENDER, MINORITY AND CHILDREN SUBJECTS:

N/A

VERTEBRATE ANIMALS:

No concerns, IACUC approval pending.

BIOHAZARDS:

No concerns

OVERALL EVALUATION:

Strengths: Very innovative proposal, attacking obesity from an unorthodox direction.

Weaknesses: The percent stenosis required for significant flow restriction through the mesentery artery is very high and it is not clear that it can be achieved by varying the stent strut properties alone. There is no established animal model for weight modulation using mesenteric ischemia. The technical challenges in the fabrication of a device that will dilate less than 50% in the center compare to the ends are not laid out and while it is noted that design modifications will be required, solutions are not proposed.

BUDGET:

Reasonable for the amount of work proposed.

CRITIQUE 3:

The stated long-term objective of this application is to improve health in individuals with morbid obesity (Body mass index >40). The specific aims are to test a novel approach at inducing weight loss in pigs by diminishing mesenteric blood flow and inducing an iatrogenic state of mesenteric insufficiency. This is accomplished by percutaneous stent placement into the Superior Mesenteric Artery (SMA) and occluding other arteries selectively by embolization.

Study animals will be compared to animals treated by sham procedure by monitoring dietary intake and weight over two months. Obesity and related medical illness is on the increase in N. America. Bariatric surgery (Gastric Bypass) is an accepted corrective measure in patients who fail traditional weight loss plans and have weight-related co-morbid illness. Minimally invasive alternatives, like the "Lap Band" are also available. Chronic mesenteric ischemia often results in post-prandial discomfort, splanchnic pain, and weight loss. However, injury or occlusion of the SMA and other mesenteric vessels can result in significant morbidity and mortality. This proposal is IACUC approved. Human subjects approval would require strong pilot data suggesting safety and efficacy.

SCIENTIFIC REVIEW ADMINISTRATOR'S NOTE:

VERTEBRATE ANIMALS (Resume): ACCEPTABLE

NOTICE: The NIH has modified its policy regarding the receipt of amended applications. Detailed information can be found by accessing the following URL address:
<http://grants.nih.gov/grants/policy/amendedapps.htm>

NIH announced implementation of Modular Research Grants in the December 18, 1998 issue of the NIH Guide to Grants and Contracts. The main feature of this concept is that grant applications (R01, R03, R21, R15) will request direct costs in \$25,000 modules, without budget detail for individual categories. Further information can be obtained from the Modular Grants Web site at <http://grants.nih.gov/grants/funding/modular/modular.htm>

MEETING ROSTER

National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

ZEB1 OSR-B (M1) R

March 14, 2007 - March 15, 2007

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

NOTIFICATION OF SCIENTIFIC REVIEW ACTION

Release Date: 04/16/2007

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593 EDDY STREET
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Our Reference: 1 R21 EB007566-01 ZEB1 OSR-B (M1)

The scientific merit review of your application, referenced above, is complete. As part of this initial review, reviewers were asked to provide written evaluations of each application and to identify those with the highest scientific merit, generally the top half of applications they customarily review, for discussion at the meeting and assignment of a priority score. Your application did not receive a score. Unscored applications are neither routinely reviewed at a second level by a national advisory council or board nor considered for funding.

Enclosed is your summary statement containing the reviewers' comments. You should call the program official listed below to discuss your options and obtain advice.

PROGRAM CONTACT:

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If you choose to resubmit, it is important to respond specifically to comments in the summary statement, as outlined in the instructions in the PHS 398 application kit (<http://grants1.nih.gov/grants/funding/phs398/phs398.html>).

Enclosure

cc: Business or institutional official of applicant organization

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